专 家 简 介

王粟明/Cissy Wang

现任职于亚什兰（中国）投资有限公司特种化学品部任产品法规专家，国际药用辅料协会（IPEC 中国）主席，亦弘商学院授课教授。负责亚太区药用辅料、食品添加剂及个人护理/家居护理产品的产品注册、法规事务、合规体系标准建立和管理及监管协调沟通等。专注于药品所使用的辅料的法规政策和策略、标准制定，合规应用及风险评价。

Cissy Suming Wang , Chair of International Pharmaceutical Excipients Council (IPEC China), Program Professor of Yeehong Business School, is working as a product regulatory professional in Ashland (China) Holding Co., Ltd. and taking in charge of the compliance management, regulatory affairs, compliance system standards establishment, and regulatory coordination& communication on pharmaceutical excipients, food additives and personal care / home care products. Specially focus on regulatory policies and strategy, standards development, and compliance applications and risk assessment for excipients used in pharmaceuticals.

胡嘉伟/Jiawei, Hu

费森尤斯医药研发（上海）有限公司高级法规事务经理，中国及亚太区法规事务（化学、生产和控制 - CMC）负责人从事法规注册工作 10 年，负责中国以及亚太区法规事务化学、生产和控制（CMC）相关工作。胡嘉伟曾就职于阿斯利康，百特和默克雪兰诺，负责新产品申报以及已上市产品法规 CMC 资料撰写、核准，公司进口药品参比制剂遴选、仿制药一致性评价以及进口产品地产化技术转移等工作，也负责国际注册包括 FDA、EMA 以及亚太区法规申报资料 CMC 部分的撰写核准；同时，配合研发和生产各技术部门日常工作，提供 CMC 部分法规的建议和意见，为产品在中国市场上是提供国内法规注册策略制定和风险评估。

Jiawei Hu, Senior Regulatory Affairs Manager is working Fresenius Medical Care R&D (Shanghai) Co., Ltd and is responsible for Chemistry, Manufacturing and Control (China and Asia Pacific) with 10-year experience in regulatory affairs. He worked as the regulatory CMC person in AstraZeneca, Baxter and Merck, was responsible for CMC documents drafting and review for IND, NDA and variation. Meanwhile the reference listed drugs application, generic quality consistency evaluation and imported drugs tech transfer were in the working scope. He was also responsible to support FDA and EMA regulatory CMC tasks. Additionally, he worked with R&D and manufacturing functions to provide CMC support, suggestion, regulatory strategy and risk assessment.

吴丽/Lilly Wu

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超过 20 年制药行业经验，曾就职于卡乐康、嘉法狮公司，从事过技术服务，质量和法规管理，以及商务运营等多个职位。作为 IPEC 中国成立的发起人之一，于 2008 年被当选为第一任主席，2015 年创立了上海欧范企业管理咨询有限公司。作为 EXCiPACT 在中国的顾问以及合作机构，程宁博士一直致力与其它相关方一起推广药用辅料第三方认证项目，向本地制药行业介绍能降低质量审核负担、提升供应链安全的合规新模式。

Nevin Cheng: Ph.D. and MBA, more than 20 years of work experiences in pharmaceutical industry, Nevin has taken various commercial roles of technical services, quality, marketing, sales and general management in Colorcon and Gattefosse. As the founder of IPEC China, he was elected as the first chair in 2008. He founded Shanghai PHEXPACT Consulting Co., Ltd. in 2015 to continue promoting initiatives of excipients in China. As the local consultant of EXCiPACT, he has been working with multiple stakeholders to promote excipient GMP&GDP 3rd party certification in order to help local pharmaceutical industry to reduce quality auditing burden and improve supply chain security.